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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/837,742

04/18/2001

Robert H. Marchessault

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12/24/2003

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,742

Applicant(s)

MARCHESSAULT ET AL.

Examiner

Pensee T. Do

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 & 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 & 7 require a complete description of the prior art method in the preambles for these claims are Jepson claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Seiver et al. (4,399,047).

Seiver et al. teaches a composition which exhibits high induced magnetism in a small applied magnetic field composed of a plurality of elongated ferromagnetic components, randomly oriented. The elongated ferromagnetic particles can be mixed with various gels and sols, set therein within a hydrogel matrix in virtually any form, as pills, tablets, beads or the like. (see col. 10, lines 18-21).

Claims 1, 2, 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Veiga et al. (Formation and Characterization of Superparamagnetic cross-linked high amylose starch; Veiga et al. Carbohydrate Polymers, 00 (1999) pages 1-5).

Veiga teaches a gelatinized cross-linked high amylose starch matrix with magnetic properties synthesized via in situ formation of iron oxides inside the polymer matrix. The composition is used in applications related to separation of bioactive molecules using molecular recognition methods. It is inherent that an immuno-reactant must be entrapped by the magnetic particles in the gelatinized matrix in a separation of bioactive molecules using molecular recognition method. (see pages 1-5). Regarding claims 8-10, these claims fail to further limit the composition of claim 1 and thus since Veiga teaches all the components of the claimed composition, it reads on these claims.

Claims 1-2, 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Gunther et al. (US 6,123,920).

Gunther teaches composite nanoparticles, comprising superparamagnetic iron oxide core provided with a coating of comprising an oxidatively cleaved starch coating. Natural starches are a combination of linear amylose and the branched amylopectin polysaccharides. While amylose content is acceptable it is preferred not so high as to cause retrogradation. The hydrophilic branched polymer is preferable because it provides dispersed precipitation seeding sites within the aqueous medium allowing uniform small precipitate particles to form. (see col. 3, line 39-col. 5, line 21). These particles can be conjugated to biotargeting agents and used for imaging the targeted tissues or organs. (see col. 2, lines 26-29).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther et al. (US 6,123,920).

Gunther has been discussed above.

However, Gunther fails to teach that the gelatinized starch granules comprising a framework of amylopectin from which amylose chains have been expelled and the matrix is permeable and has accessible interior surfaces defining a cage for physical or chemical entrapment of antigens or antibodies.

Gunther teaches that the use of non-branched hydrophilic polymers is not effective. (see col. 4, lines 35-40). Since Natural starches have linear amylose and branched amylopectin, it would have been obvious to one of ordinary skills in the art to cleave the linear amylose and just use the branched amylopectin as a more effective matrix. Although amylose is acceptable but not so high. Thus, for a more effective result and to avoid high contents of amylose, it would have been obvious to one of ordinary skills in the art to expel the amylose chains. Furthermore, high content of amylose causes retrogradation. Regarding the cage for physical/chemical entrapment of antigens or antibodies, since Gunther teaches that the magnetic particles are within the hydrogel matrix and the biotargeting agents need to be conjugated with the magnetic

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particles, one of ordinary skills in the art would find it obvious that the matrix must be permeable and has accessible interior surfaces for the biotargeting agents to reach the magnetic particles within said matrix.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
December 12, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641